RISK ASSESSMENT GUIDANCE FOR SUPERFUND, PART F: AN OVERVIEW

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National Forum on Vapor Intrusion

January 13, 2009

Topics

- Purpose of the document
- Project history
- Workgroup members
- Comparison of previous and updated inhalation methodologies
- Examples of RAGS F implementation
- FAQs
- Timeline going forward

Purpose of Document

- To update and supersede existing Superfund (SF) guidance on calculating cancer and non-cancer risk from contaminant exposures through the inhalation route (e.g., RAGS, Part A) to be consistent with updated science concerning inhalation dosimetry.
- Document endorses the use of the Reference Concentration (RfC) and Inhalation Unit Risk (IUR) approach to inhalation risk assessment instead of the use of Inhalation Reference Doses (RfD_is) and inhalation Cancer Slope Factors (CSF_is).
- Document provides recommendations concerning key issues in inhalation risk assessment (e.g., route-to-route extrapolation).

Project History

- **October 1994 –** EPA publishes "Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry."
- **July 1996 & December 2002** – EPA publishes Soil Screening Guidance documents implementing the RfC/IUR approach in developing risk-based Soil Screening Levels (SSLs) for volatile contaminants.
- **September 2003** - EPA Workshop, "Inhalation Risk Assessment: A Superfund Focus." Strawman document presented.
- **Fall 2004** - Industrial Economics (IEc) updates Strawman based on comments and discussion from workshop. Outline of draft guidance document prepared.
- **Spring 2005** – Inhalation risk workgroup established. Draft guidance document prepared by IEc for distribution to EPA workgroup.
- **Summer 2005** – Draft guidance document distributed to EPA workgroup members. Bi-weekly conference calls begin to discuss key issues.
- **Spring 2006** – Bi-weekly workgroup meetings conclude. IEc begins to incorporate consensus decisions made by the group into the document.

Project History (Cont.)

- **Summer 2006** – Workgroup reviews revised version of RAGS F and comes to a consensus on edits to be made.
- **December 2006** – Office of the General Council (OCG) review.
- **July 2007** – Begin internal EPA review.
- **Fall 2007** – Subgroup of workgroup members convene to discuss internal EPA review comments.
- **January 2008** – “Fatal flaws” review within full workgroup.
- **March 2008** – Begin external peer and State review.
- **June 2008** – Workgroup convenes to address comments received during external peer and State review.
- **September 2008** – EPA, with support from IEc, incorporates external peer and State review comments into new version of document.
- **Winter 2008** – Concurrence review complete.

Workgroup Members

- Dave Crawford (OSWER/OSRTI)*
- Michael Sivak (Region 2)*
- Brenda Foos (OCHP)
- Gary Foureman (ORD/NCEA)
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Previous Approach Compared to Updated Approach: Carcinogens

Previous Approach (RAGS, Part A):

Chronic Daily Intake = CA x (IR/BW) x (ET x EF x ED)/AT

Cancer Risk = Intake x CSF_i

Updated Approach (1994 Guidance):

Exposure Concentration (EC) = (CA x ET x EF x ED)/AT

Cancer Risk = EC x IUR

Where: CA = concentration in air; IR = Inhalation Rate; BW = bodyweight; ET = exposure time; EF = exposure frequency; ED = exposure duration; AT = averaging time; CSF_i = inhalation cancer slope factor; and IUR = inhalation unit risk.

Previous Approach Compared to Updated Approach: Non-Carcinogens

Previous Approach (RAGS, Part A):

Chronic Daily Intake = CA x (IR/BW) x (ET x EF x ED)/AT

Hazard Quotient (HQ) = Intake/RfD_i

Updated Approach (1994 Guidance):*

Exposure Concentration (EC) = (CA x ET x EF x ED)/AT

HQ = EC/RfC

Where: CA = concentration in air; IR = Inhalation Rate; BW = bodyweight; ET = exposure time; EF = exposure frequency; ED = exposure duration; AT = averaging time; RfD_i = inhalation reference dose; and RfC = reference concentration.

* = this example assumes a chronic exposure scenario

Exposure Scenario Examples

- Hypothetical site contaminated with Benzene
- Residential and Commercial/Industrial (chronic)
  - Chronic CA = 100 µg/m^3
  - IUR from IRIS = Range from 2.2E-6 to 7.8E-6 per µg/m^3
  - RfC from IRIS = 3E-2 mg/m^3 = 30 µg/m^3
- Trespasser (intermittent)

Residential Exposure Scenario Example

Cancer Risk:

$EC = [CA \times ET \times EF \times ED]/AT$

$EC = [100\ \mu g/m^3 \times 24\ h/d \times 350\ d/y \times 30\ y]/[70\ y \times 24\ h/d \times 365\ d/y]$

$EC = 41\ \mu g/m^3$

Cancer Risk = EC x IUR = $41\ \mu g/m^3 \times 7.8E\text{-}6$ = **3.2E-4**

Non-Cancer Hazard:

$EC = [CA \times ET \times EF \times ED]/AT$

$EC = [100\ \mu g/m^3 \times 24\ h/d \times 350\ d/y \times 30\ y]/[30\ y \times 24\ h/d \times 365\ d/y]$

$EC = 96\ \mu g/m^3$

HQ = EC/RfC = $96\ \mu g/m^3 / 30\ \mu g/m^3$ = **3.2**

Commercial/Industrial Exposure Scenario Example

Cancer Risk:

EC = [CA x ET x EF x ED]/AT

EC = [100 µg/m^3 x 8 h/d x 250 d/y x 25 y]/[70 y x 24 h/d x 365 d/y]

EC = 8.2 µg/m^3

Cancer Risk = EC x IUR = 8.2 µg/m^3 x 7.8E-6 = **6.4E-5**

Non-Cancer Hazard:

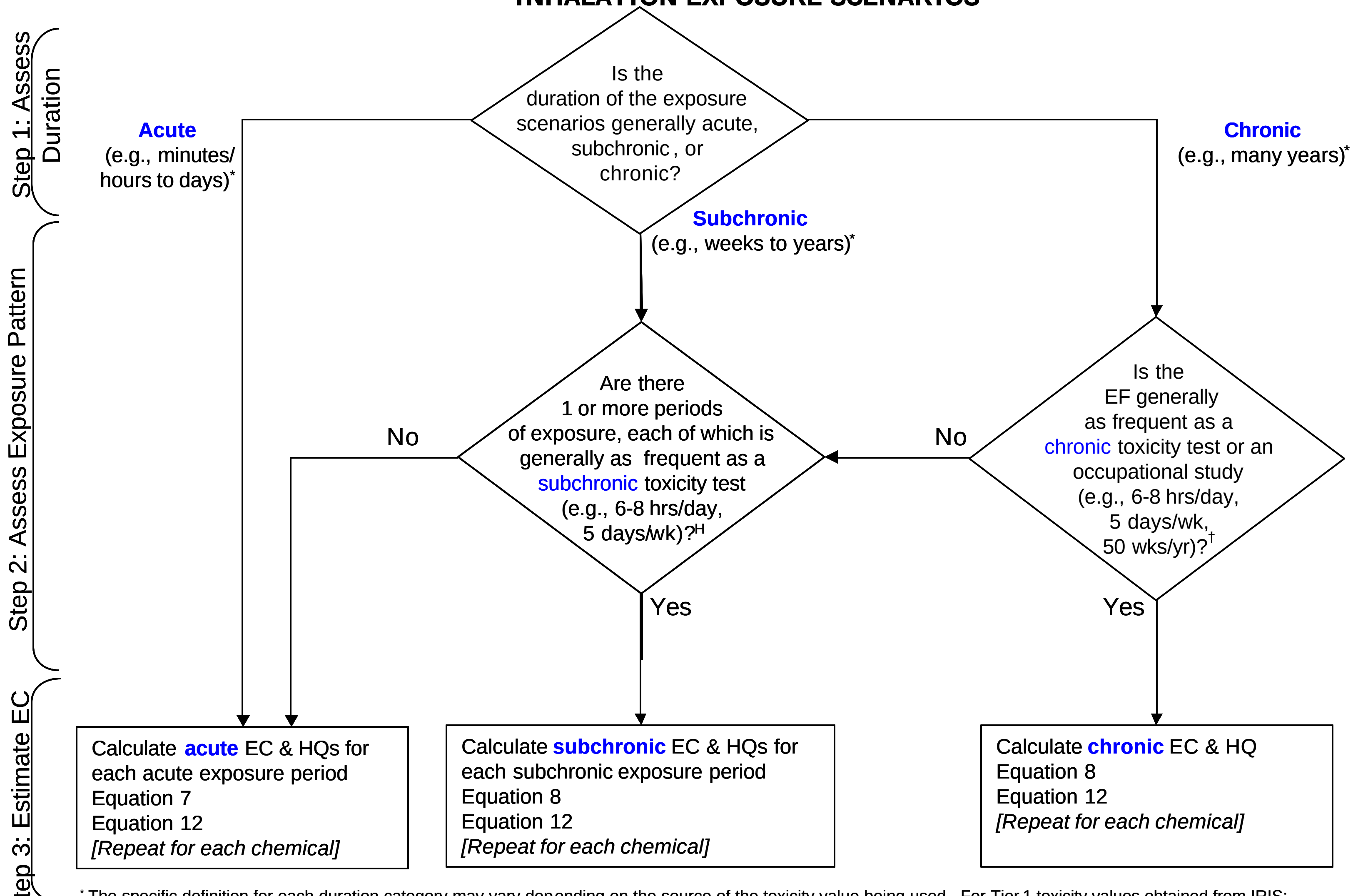
EC = [CA x ET x EF x ED]/AT

EC = [100 µg/m^3 x 8 h/d x 250 d/y x 25 y]/[25 y x 24 h/d x 365 d/y]

EC = 23 µg/m^3

HQ = EC/RfC = 23 µg/m^3/30 µg/m^3 = **0.8**

FIGURE 2
RECOMMENDED PROCEDURE FOR DERIVING EXPOSURE CONCENTRATIONS AND HAZARD QUOTIENTS FOR INHALATION EXPOSURE SCENARIOS



* The specific definition for each duration category may vary depending on the source of the toxicity value being used. For Tier 1 toxicity values obtained from IRIS:

acute exposures are defined as those lasting 24 hours or less;

subchronic exposures are defined as repeated exposures for more than 30 days, up to approximately 10 percent of the life span in humans; and

chronic exposures are defined as repeated exposures for more than approximately 10 percent of the life span in humans (EPA, 2008).

For the purposes of this document, short-term exposures, defined by the IRIS glossary as repeated exposures for more than 24 hours, up to 30 days, should be treated as subchronic.

H Exposure regimens vary from study to study. Risk assessors should use best professional judgment to determine if the exposure pattern in a given scenario is reasonably similar to a typical regimen for a chronic or subchronic study.

Trespasser Exposure Scenario Example

- Acute CAs = 1-h samples: 200 µg/m^3, 120 µg/m^3, 95 µg/m^3; 8-h samples: 80 µg/m^3, 100 µg/m^3, 110 µg/m^3
- CalEPA Acute Reference Exposure Level (REL) = 1,300 µg/m^3 (based on 6-h exposure)

Trespasser Exposure Scenario Example (Cont.)

Cancer Risk:

EC = [CA x ET x EF x ED]/AT

EC = [100 $\mu g/m^3$ x 2 h/d x 100 d/y x 2 y]/[70 y x 24 h/d x 365 d/y]

EC = 0.07 $\mu g/m^3$

Cancer Risk = EC x IUR = 0.07 $\mu g/m^3$ x 7.8E-6 = **5.5E-7**

Non-Cancer Hazard:

EC = CA (for each acute exposure period)

EC = 200 $\mu g/m^3$ OR 110 $\mu g/m^3$

HQ = EC/REL_{acute} = 200 $\mu g/m^3$/1,300$\mu g/m^3$ = **0.15** OR

= 110 $\mu g/m^3$/1,300$\mu g/m^3$ = **0.09**

TABLE 5.2
NON-CANCER TOXICITY DATA -- INHALATION
The Dean Company

Chemical of Potential Concern	Chronic/ Subchronic	Inhalation RfC		Extrapolated RfD		Primary Target Organ(s)	Combined Uncertainty/Modifying Factors	RfC : Target Organ(s)	
		Value	Units	Value	Units			Source(s)	Date(s) (MM/DD/YYYY)
4,4'- DDD	NA	NA	NA			NA	NA	NA	NA
4,4'-DDE	NA	NA	NA			NA	NA	NA	NA
4,4'-DDT	NA	NA	NA			NA	NA	NA	NA
Bis(2-ethylhexyl)phthalate	NA	NA	NA			NA	NA	NA	NA
Chloroform	Chronic	3E-04	mg/m3			Nasal	1000	NCEA	6/21/2001
Chloroform	Subchronic	3E-03	mg/m3			Nasal	100	NCEA	6/21/2001
Heptachlor	NA	NA	NA			NA	NA	NA	NA
Aluminum	Chronic	5E-03	mg/m3			CNS	300	NCEA	6/21/2001
Barium	Chronic	5E-04	mg/m3			Fetus	1000	HEAST	7/1/1997
Barium	Subchronic	5E-03	mg/m3			Fetus	100	HEAST	7/1/1997
Copper	NA	NA	NA			NA	NA	NA	NA
Iron	NA	NA	NA			NA	NA	NA	NA
Lead	NA	NA	NA			NA	NA	NA	NA
Manganese (nonfood)	Chronic	5E-05	mg/m3			CNS	1000	IRIS	6/21/2001

Definitions: NA = Not Availabile
IRIS = Integrated Risk Information System
HEAST = Health Effects Assessment Summary Table, July 1997
NCEA = National Center for Environmental Assessment

TABLE 6.2
CANCER TOXICITY DATA -- INHALATION
The Dean Company

Chemical of Potential Concern	Unit Risk		Inhalation Cancer Slope Factor		Weight of Evidence/ Cancer Guideline Description	Unit Risk : Inhalation CSF	
	Value	Units	Value	Units		Source(s)	Date(s) (MM/DD/YYYY)
4,4'- DDD	NA	NA			NA	NA	NA
4,4'-DDE	NA	NA			NA	NA	NA
4,4'-DDT	9.7E-05	1/ug/m3			B2	IRIS	06/21/01
Bis(2-ethylhexyl)phthalate	NA	NA			NA	NA	NA
Chloroform	2.3E-05	1/ug/m3			B2	IRIS	06/21/01
Heptachlor	1.3E-03	1/ug/m3			B2	IRIS	06/21/01
Aluminum	NA	NA			NA	NA	NA
Barium	NA	NA			NA	NA	NA
Barium	NA	NA			NA	NA	NA
Copper	NA	NA			NA	NA	NA
Iron	NA	NA			NA	NA	NA
Lead	NA	NA			NA	NA	NA
Manganese (nonfood)	NA	NA			NA	NA	NA

Definitions: NA = Not Availabile
IRIS = Integrated Risk Information System
B2 = Probably Human Carcinogen - indicates sufficient evidence
in animals and inadequate or no evidence in humans

Inhalation Screening Levels

- RAGS F provides equations for calculating target contaminant concentrations in air.
- RAGS F also discusses target concentrations in other media, such as soil, tap water, and soil gas or ground water values for vapor intrusion.

Inhalation Screening Levels (Cont.)

TABLE 4 RECOMMENDED PROCEDURE FOR CALCULATING RISK-BASED SCREENING CONCENTRATIONS FOR CONTAMINANTS IN AIR		
	Cancer Risk-Based	**Hazard-Based**[1]
Step 1: Select Target Levels	Select target cancer risk (e.g., 1 x 10^{-6}).	Select target HQ (e.g., 1).
Step 2: Identify Toxicity Value[2]	Identify inhalation cancer potency value (e.g., IUR). If none exists, proceed with hazard-based screening level calculation.	Identify inhalation reference value (e.g., RfC) to match exposure scenario (acute, subchronic, chronic). If none exist, proceed with cancer screening level calculation.
Step 3: Calculate CA	Using target cancer risk from Step 1 along with the receptor- and scenario-specific exposure parameter values, calculate CA; the following equation is recommended: CA = (AT x Target Risk)/(IUR x ET x EF x ED)	Using target HQ from Step 1 along with the receptor- and scenario-specific exposure parameter values, calculate CA; the following equation is recommended: CA = (AT x Target HQ x RfC x 1000 µg/mg)/(ET x EF x ED)
Step 4: Select Screening Concentration	Select minimum of predicted cancer risk- and hazard-based values as screening concentrations.[3] Repeat for each receptor/scenario combination of interest.	

FAQ: Inhalation Risk Assessment for Children

- Application of Age-Dependant Adjustment Factors (ADAFs) recommended for chemicals with a mutagenic mode of action (MMOA) if no child-specific IUR exists on IRIS or PPRTV (per the Supplemental Cancer Guidelines).
- No other adjustments to inhalation toxicity values recommended when assessing risk to children.
- Activity patterns for children may differ, potentially leading to higher exposures (e.g., outdoor play). This will be addressed as part of the exposure assessment and reflected in the calculations of the EC.

FAQ: Inhalation Risk Assessment for Children (Cont.)

- As part of the risk characterization process, risk assessors can identify site-specific subpopulations sensitivities.
- RAGS F presents a comparison of a Human Equivalent Concentration (HEC) calculated with the EPA default parameters with HECs calculated using age- and activity group-specific parameters (Appendix A).

FAQ: Availability of Inhalation Toxicity Values

- RAGS F discourages risk assessors from performing route-to-route extrapolation using default body weight and inhalation rate parameters.
- RAGS F recommends risk assessors contact NCEA'S Superfund Health Risk Technical Support Center (STSC) to pursue an alternate value through PBPK modeling or a surrogate chemical for SF site analyses.
- If no alternate value is available, document recommends performing a qualitative risk assessment, noting the lack of information in the uncertainty section.

FAQ: Availability of Inhalation Toxicity Values (Cont.)

- Regional Screening Levels for Chemical Contaminants at Superfund Sites
  - 134 RfCs
  - 138 IURs
- IRIS
  - 72 RfCs
  - 54 IURs

Next Steps

- Workgroup has completed consensus review.
- Document is awaiting release.